



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 84

[Docket Number CDC-2015-0004; NIOSH-280]

RIN 0920-AA60

Closed-Circuit Escape Respirators; Extension of Transition Period

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Interim final rule.

SUMMARY: In March 2012, the Department of Health and Human Services (HHS) published a final rule establishing new standards for the certification of closed-circuit escape respirators (CCERs) by the National Institute for Occupational Safety and Health (NIOSH) within the Centers for Disease Control and Prevention (CDC). The new standards were designed to take effect over a 3-year transition period. HHS has determined that extending the concluding date for the transition is necessary to allow sufficient time for respirator manufacturers to meet the demands of the mining, maritime, railroad, and other industries. Pursuant to this interim final rule, NIOSH will extend the phase-in period until 6 months after the date that the first approval is granted to certain CCER models.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by "RIN 0920-AA60," by any of the following methods:

- **Internet:** Access the Federal e-rulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, OH 45226-1998.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All relevant comments will be posted without change to <http://www.regulations.gov> including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst; 1090 Tusculum Ave, MS: C-46, Cincinnati, OH 45226; telephone (855)818-1629 (this is a toll-free number); email NIOSHregs@cdc.gov.

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Interim Final Rule

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, arguments, recommendations, and data. Comments are invited on any topic related to this rulemaking. HHS invites comments specifically on the following question related to this rulemaking:

1. Will a compliance date 6 months after the date that the first approval is granted in each of three categories of CCER types provide sufficient time for respirator manufacturers to develop production capacity to meet expected market demand, while not causing undue loss of sales revenue that may be expected from achieving the first successful design for the given size?

II. Background

A. History of Rulemaking

Under 42 CFR Part 84--Approval of Respiratory Protective Devices, NIOSH approves respirators used by workers in mines and other workplaces for protection against hazardous atmospheres. The Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA) require U.S. employers to supply NIOSH-approved respirators to their employees whenever the employer requires the use of respirators.

A closed-circuit escape respirator (CCER) is an apparatus in which the wearer's exhalation is rebreathed after the carbon dioxide in the exhaled breath has been effectively removed and a suitable oxygen supply has been restored from sources composed of compressed, chemical, or liquid oxygen. CCERs are used in certain industrial and other work settings during emergencies to enable users to escape from atmospheres that can be immediately dangerous to life and health. The CCER, known in the mining industry as a self-contained self-rescuer, is used by miners to escape dangerous atmospheres in mines. It is also used by certain Navy and Coast Guard personnel, such as crews working below decks on vessels, where it is referred to as an emergency escape breathing device, and in the railroad industry, where it is known as an emergency escape breathing apparatus. To a lesser extent, it is also used by other workers who work underground or in confined spaces, such as in tunneling operations in the construction industry.

Standards for the certification of CCERs were updated in a 2012 final rule, in which HHS codified a new Subpart O and removed only those technical requirements in 42 CFR part 84--Subpart H that were uniquely applicable to CCERs. All other applicable requirements of 42 CFR part 84 were unchanged. The purpose of these updated requirements is to enable NIOSH and MSHA to more effectively ensure the performance, reliability, and safety of CCERs.

The effective date for the new standards in Subpart O was April 9, 2012. Beginning on that date, any new application for a

certification of approval for a CCER would be required to meet the new standards in Subpart O. Manufacturers were allowed to continue to manufacture, label, and sell respirators certified to the prior Subpart H standard until April 9, 2015.

B. Need for Rulemaking

HHS has determined that extending the concluding date for the transition is necessary to allow sufficient time for respirator manufacturers to meet the demands of the mining, maritime, railroad, and other industries. NIOSH has found that respirator manufacturers that have submitted applications under the Subpart O standards have not been successful in meeting those standards and obtaining approval of any large-capacity CCERs. While one manufacturer recently received NIOSH approval for a small-capacity non-mining respirator, large-capacity units designed for underground coal mining and other industries are not likely to receive NIOSH approval before the April 9, 2015 deadline. Mining industry and maritime stakeholders have expressed concern that an adequate number of new CCERs will not be available for purchase by April 2015, when the grandfather clause is set to expire, leaving miners, sailors, and other workers with insufficient protection.

C. Scope

Pursuant to this interim final rule, which amends 42 CFR 84.301, NIOSH will extend the deadline for Subpart O compliance until 6

months after the date on which NIOSH approves the first CCER in each of the following three categories, described in 42 CFR 84.304: Cap 1 mining, Cap 3 mining, and Cap 3 non-mining.

CCER Cap 1 non-mining and Cap 2 mining and non-mining categories are not included in this rulemaking. Approval TC-13G-0001 was issued to Avon Protection Systems, Inc. on July 24, 2014 for its ER-2 emergency escape breathing device (EEBD). The ER-2 EEBD is certified by NIOSH as a Cap 1, 20-liter, CCER for use in non-mining applications. The current deadline for compliance (April 9, 2015) already provides for more than a 6-month period for the issuance of additional approvals for respirators in this category. Therefore, NIOSH has determined no further extension of the existing April 9, 2015 deadline is required for the Cap 1 non-mining category. The Cap 2 mining and non-mining categories are not included in this rulemaking because NIOSH never approved any respirators under the former Subpart H requirements that would be classified within either of these two categories.

III. Issuance of an Interim Final Rule with Immediate Effective Date

Rulemaking under the Administrative Procedure Act (APA) generally requires a public notice and comment period and consideration of the submitted comments prior to promulgation of a final rule (5 U.S.C. 553). However, the APA provides for exceptions to its notice and comment procedures when an agency finds that there is good cause for

dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. In accordance with the provisions in 5 U.S.C. 553(b)(3)(B), HHS finds good cause to waive the use of prior notice and comment procedures for this IFR and to make this action effective immediately.

This IFR amends 42 CFR 84.301 to extend the concluding date for the Subpart O transition to allow sufficient time for respirator manufacturers to meet the supply demands of the mining, maritime, railroad, and other industries. Pursuant to this interim final rule, NIOSH will extend the deadline for Subpart O compliance until 6 months after the date on which NIOSH approves the first CCER in each of three categories. HHS has determined that it is impracticable to use prior notice and comment procedures for this IFR because the transition period will end on April 9, 2015, and respirator manufacturers must have sufficient notice that they may be granted an extension. Thus, HHS is waiving the prior notice and comment procedures in the interest of protecting the health of coal miners and workers in other industries that use CCERs by offering extensions to manufacturers to ensure that the supply of new CCERs will not be depleted after April 9, 2015.

Stakeholders were given an opportunity to comment on the CCER notice of proposed rulemaking, published on December 10, 2008 (73 FR 75027), in which HHS proposed that all CCERs submitted to NIOSH for approval on or after the effective date would adhere to the new standards; all CCERs sold after 3 years would adhere to the new

standards; and all certificates of approval under the former standard would be rescinded at 6 years. In response to stakeholder comments, HHS determined that the products certified under the former standard could remain in service through the service time indicated by the manufacturer (typically, 10-15 years), rather than those approvals being rescinded at 6 years, and that retaining the 3-year transition period would address the needs of workplace managers to have a sufficient supply of CCERs while ostensibly giving respirator manufacturers sufficient time to develop new products in accordance with the new standards. With the April 9, 2015 deadline approaching, manufacturers and other stakeholders have expressed concerns that no new products certified to the Subpart O requirements have yet become available. During a NIOSH status update at a MSHA meeting held on June 19, 2014, participating stakeholders were given an additional opportunity to provide input to NIOSH and MSHA, where they expressed concern about the manufacturers' inability to submit respirators to NIOSH for approval prior to the concluding date of the transition period. A majority of manufacturers who have offered input to NIOSH indicate that they will not be able to build enough capacity of units submitted under Subpart O to meet market demands prior to the April 9, 2015 deadline.

Under 5 U.S.C. 553(d)(3), HHS finds good cause to make this IFR effective immediately. As stated above, in order to protect the health of coal miners and workers in other industries, it is necessary that HHS act quickly to amend 42 CFR 84.301 to allow NIOSH

to offer transition period concluding date extensions on a case-by-case basis. While amendments to 42 CFR 84.301 are effective on the date of publication of this IFR, they are interim and will be finalized following the receipt and consideration of any substantive public comments. (See Section I. Public Participation, above.)

IV. Summary of Interim Final Rule

This interim final rule amends 42 CFR 84.301 to allow NIOSH to extend the original 3-year period for continued manufacturing, labeling, and sale of CCERs approved under Subpart H to allow for the orderly implementation of the new testing and certification requirements of Subpart O. This provision allows NIOSH to extend the original transition period to allow manufacturers to obtain NIOSH certification, establish production capacity, and complete the modification of existing CCER designs, if necessary, or develop entirely new designs that respond to the new testing and certification requirements. An extension also ensures that a constant supply of approved CCERs will remain available for purchase. The new Subpart O standards will continue to be applied to all new CCER designs that are submitted for approval.

Paragraph (a) of this section is new, and authorizes the continued manufacturing, labeling, and selling of CCERs approved under the former standards in Subpart H until either April 9, 2015 or 6 months after the date that NIOSH first approves a CCER model under

the capacity rating categories Cap 1 (for mining applications) and Cap 3 (mining and non-mining) described in 42 CFR 84.304, whichever date comes later. In particular, the compliance deadline may be extended for only those types of CCER that are currently approved under the former standards in Subpart H: 20-minute non-mining units and 10-minute and 1-hour units approved for mining pursuant to 42 CFR 84.100. As discussed in the final rule published on March 8, 2012, 10-minute units are considered comparable to Cap 1 devices, and 1-hour units are comparable to Cap 3 devices (77 FR 14168).

A new paragraph (b) clarifies that any non-major modifications to those approved devices must continue to meet the prior Subpart H standards. CCERs with major modifications that will result in a new NIOSH approval must conform to the new Subpart O standards.

Paragraph (c) of this section is unchanged from the current requirement that Subpart O applies to all CCERs submitted to NIOSH for approval after the effective date of the final rule, April 9, 2012.

V. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental,

public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This interim final rule is not being treated as a "significant" action under E.O. 12866. It amends existing 42 CFR 84.301 to allow NIOSH to extend the deadline for respirator certification standards established in 2012, and does not result in any costs to affected stakeholders. Accordingly, HHS has not prepared an economic analysis and the Office of Management and Budget (OMB) has not reviewed this rulemaking.

The rule does not interfere with State, local, or tribal governments in the exercise of their governmental functions.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The Department of Health and Human Services (HHS) certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities, including both small manufacturers of CCERs and the small mining operators that are required to purchase them, within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 et seq., requires an agency to invite public comment on and to obtain OMB approval of any rule of general applicability that requires recordkeeping, reporting, or disclosure requirements.

NIOSH has obtained approval from OMB to collect information from respirator manufacturers under "Information Collection Provisions in 42 CFR Part 84--Tests and Requirements for Certification and Approval of Respiratory Protective Devices" (OMB Control No. 0920-0109, exp. November 30, 2017), which covers information collected under 42 CFR Part 84. This rulemaking does not increase the reporting burden on respirator manufacturers.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), the Department will report the promulgation of this rule to Congress prior to its effective date. The report will state that the Department has concluded that this rule is not a "major rule" because it is not likely to result in an annual effect on the economy of \$100 million or more.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 et seq.) directs agencies to assess the effects of Federal

regulatory actions on State, local, and tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased annual expenditures in excess of \$100 million by State, local or tribal governments in the aggregate, or by the private sector. For 2014, the inflation-adjusted threshold is \$152 million.

F. Executive Order 12988 (Civil Justice)

This rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. NIOSH has provided clear deadline extension requirements that will be applied uniformly to all applications from manufacturers of CCERs. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, HHS has evaluated the environmental health and safety effects of this rule on children. HHS has determined that the rule would have no effect on children.

I. Executive Order 13211 (Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, HHS has evaluated the effects of this rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law No. 111-274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating the interim final rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 84

Incorporation by reference, Mine safety and health, Occupational safety and health, Personal protective equipment, Respirators.

Interim Final Rule

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR Part 84 as follows:

PART 84--APPROVAL OF RESPIRATORY PROTECTIVE DEVICES

1. The authority citation for Part 84 is revised to read as follows:

Authority: 29 U.S.C. 651 et seq., 30 U.S.C. 3, 5, 7, 811, 842(h), 844.

2. Revise § 84.301 to read as follows:

§ 84.301 Applicability to new and previously approved CCERs.

(a) The continued manufacturing, labeling, and sale of CCERs previously approved under Subpart H is authorized for units with durations comparable to Cap 1 (for mining applications) and Cap 3 (mining and non-mining applications) until either April 9, 2015 or 6 months after the date of the first NIOSH approval of a respirator model under each respective category specified, whichever date comes later.

(b) Any manufacturer-requested modification to a device approved under the former subpart H standards must comply with the former

subpart H standards and address an identified worker safety or health concern to be granted an extension of the NIOSH approval. Major modifications to the configuration that will result in a new approval number must meet and be issued approvals under the requirements of this subpart O.

(c) This subpart O applies to all CCERs submitted to NIOSH for a certificate of approval after April 9, 2012.

Dated: January 14, 2015.

Sylvia M. Burwell,
Secretary, Department of Health and Human Services.

Billing Code: 4163-18-P

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